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| 10/806,961 | 03/23/2004 | Greg Marik | 31132.195 | 2351 |
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| HAYNES AND BOONE, LLP | | | EXAMINER | |
| 901 Main Street | | | MILLER, CHERYL L | |
| Suite 3100 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/806,961

Applicant(s)

MARIK ET AL.

Examiner

Cheryl Miller

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 9, 11, 14-18, 24-26 and 29-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 9, 11, 14-18, 24-26, and 29-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 30, 2007 has been entered.

Response to Arguments

Applicant's arguments filed October 30, 2007 have been fully considered but they are not persuasive. The applicant has argued that there is support in the drawings for the 112 1st P rejections, specifically in figures 5-6 and 7-8. Although figures 2-6 may show a curvature "substantially similar", neither figures 5-6 or 7-8 seem to show a "larger radius". Figures 7-8 do not even seem to have a curvature at on the fifth surface, it seems flat. Further, figures 7-8 are a non-elected embodiment and the claims should be directed to the original elected embodiment only.

The applicant has also argued that Zdeblick (US 2002/0082701 A1) does not disclose a second curvature smaller than the first curvature. The examiner disagrees. The first curvature seems to have a flatter curve than the first curvatures. Further, Zdeblick discloses the intermediate lobe (curve at the second and fourth curvature) to be adjustable to different widths, smaller or larger, and with a smaller width, the second curvature will inherently be smaller, see P0083 and P0112.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7, 9, 11, 14-18, 24-26, and 29-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites, "and the convex outer portion having a fifth radius of curvature substantially similar to or *larger* than the first radius of curvature". This limitation was not found in the specification. No mention of a fifth curvature in comparison to a first curvature was found in the specification, let alone a fifth curvature period. Although figures 5 and 6 show the curvatures seem fairly similar, it is difficult to tell the exact curvatures from the figures. The figures certainly do not show support for "or larger", (which encompasses the first curvature and larger to infinity) as a full range of curvatures bigger than center members top surface has not been shown or disclosed. Claims 2-4, 7, 9, 11, 14-18, 24-26, and 29-34 depend upon claim 1 and inherit all problems with the claim.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim recitation, "surface having a fifth radius of curvature substantially equal to the first radius of curvature" lacks antecedent basis in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 9, 14-18, 24-25, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Zdeblick et al. (US 2002/0082701 A1, cited previously). See figure 16 and respective portions of the specification. Zdeblick discloses an implant (110) comprising a first member (112) comprising a concave recess (recess of first lobe see attachment 1) a second member (114) having a convex projection (intermediate lobe, see attachment 1) with a smaller radius than the concave recess (see fig. 16, intermediate lobe appears a bit narrower, thus has a smaller curvature, see also, P0083 and P0112 which disclose different sizing for the intermediate lobe, which inherently causes a change in curvature, the sizing being smaller or larger), and a center member (spacer 116) having a convex surface (first lobe of 116) for mating with the concave recess and a concave center portion (intermediate lobe of 116) and convex outer portion (first lobe of 116) to mate with the second member having similar curvatures, see attachment 1 cited in previous office action. The lobes are disclosed to be partly cylindrical, thus have constant radii.

Claims 1-4, 7, 9, 11, 14-18, 24-26, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Judet (US 5,314,485, cited previously). Judet discloses an implant (1) comprising a first member (2) comprising a concave recess (23) a second member (4) having a convex projection (40) with a smaller radius than the concave recess (see fig. 1, 2), and a center

member (3) having a convex surface (barrel surface) for mating with the concave recess and a concave center portion (32) and convex outer portion (barrel surface) to mate with the second member having similar curvatures. See figures 1 and 2 for remaining dependent claims.

Claims 1-4, 7, 9, 11, 14-18, 24-26, 29-34 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Sennwald et al. (US 5,507,821). See figures 1, 2 and respective portions of the specification. Sennwald discloses an implant *capable of* placement in an intervertebral location comprising a first member (18) having a first concave curvature (5), a second member (1) having a convex second curvature smaller than the first (see fig.1), and a center member (2) having a convex third surface (4) similar to the first surface, and a fourth surface having a concave center portion (3) and outer convex portion (seen in dashed lines in fig.2) similar to the first, wherein the first and second members are able to translate relative one another. Sennwald discloses a sidewall connecting the third (4) and fourth (3) surface that is cylindrical (see figs.1, 2).

Claims 1, 7, 9, 14-18, 24-26, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Casutt (US 2003/0045939 A1). Casutt discloses an intervertebral implant (fig.1, 3) comprising a first member (2) having a first concave curvature (right or left recess of 2), a second member (1) having a convex second curvature (middle protrusion) smaller than the first (see fig.1; first curvature appears to be flatter curve), and a center member (3) having a convex third surface (right or left convexity on the bottom of 3) similar to the first surface, and a fourth surface (top surface of 3) having a concave center portion (middle of 3) and outer convex portion

(top surface of 3 on right or left) similar to the first, wherein the first and second members are able to translate relative one another.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casutt (US 2003/0045939 A1). Casutt discloses the intervertebral implant substantially as claimed however has shown the center member to have a somewhat kidney shaped sidewall rather than a circular/cylindrical sidewall as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a circular/cylindrical periphery since such a modification would have involved a mere change in the shape of the component. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/



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